

REMARKS

Reconsideration and withdrawal of the rejections of this application and consideration and entry of this paper are respectfully requested in view of the herein remarks and accompanying information, which place the application in condition for allowance.

I. STATUS OF CLAIMS AND FORMAL MATTERS

The specification is amended to correct the length of the Abstract.

No new matter is added.

Claims 1-67 are currently under consideration. Claims 1, 5, 8 and 9 are amended, claims 15-67 are cancelled, and claim 68 and 69 are newly added without prejudice, without admission, without surrender of subject matter, and without any intention of creating any estoppel as to equivalents.

No new matter is added.

Applicants note that the cancellation of claims 15-67 relate to the election of the claims of Group I (claims 1-14) that was submitted in the Response to Office Action filed on November 1, 2006. Newly added claims 68 and 69 are product-by-process claims which depend from and therefore include all the limitations of claim 1.

It is submitted that the claims herewith are patentably distinct over the prior art, and these claims are in full compliance with the requirements of 35 U.S.C. § 112. The amendments to the claims presented herein are not made for purposes of patentability within the meaning of 35 U.S.C. §§ 101, 102, 103 or 112. Rather, these amendments and additions are made simply to clarify the scope of protection to which Applicants are entitled.

Support for the amended claims can be found throughout the specification and claims as originally filed. Support for amended claim 1 can be found, for instance, in the paragraphs beginning on page 13, line 17, and on page 32, line 19, in Example 3, and in claim 7 as originally filed. Support for amended claim 9 can be found, for example, in the paragraph beginning on page 31, line 16, and in Example 1. Support for newly added claim 68 can be found, for instance, in the paragraphs beginning on page 10, line 21, on page 14, line 19, and on page 34, line 6, and in Example 3. Support for newly added claim 69 can be found, for example, in the paragraphs beginning on page 10, line 21, on page 14, line 19, and on page 35, line 5.

II. OBJECTION TO THE SPECIFICATION IS OVERCOME

The specification is objected for allegedly presenting an abstract that is over 150 words. In response, Applicants amend the specification herein, such that the Abstract is 150 words or less in length. Accordingly, reconsideration and withdrawal of the objection to the specification are respectfully requested.

III. REJECTIONS UNDER 35 U.S.C. § 112, 2ND PARAGRAPH ARE OVERCOME

Claims 1-14 were rejected under 35 U.S.C. § 112, second paragraph as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. This rejection is respectfully traversed.

Firstly, the Office Action contends that claims 1-14 were vague and indefinite for failing to recite clear and distinct process steps for carrying out the method, as there is allegedly only one step. In response, Applicants draw attention to the amendment to claim 1, notably that the claim herein recites two distinct steps comprising preparing a support structure and culturing cells. Thus, claim 1, as well as claims 2-14 which are dependent upon claim 1, clearly defines the process steps for carrying out the disclosed method.

Secondly, the Office Action asserts that claim 4 recites language containing terminology that is indefinite and that claim 4 does not further limit the invention of claim 1. Applicants note that claim 4 is canceled herein, which thereby obviates this rejection.

Finally, claim 9 is allegedly vague and indefinite for the recitation of "or their alternatives" as it is unclear what defines the alternatives. Applicants herein amend claim 9, such that "or their alternatives" is not recited.

Accordingly, reconsideration and withdrawal of all of the rejections under 35 U.S.C. § 112, second paragraph, are respectfully requested

IV. REJECTIONS UNDER 35 U.S.C. § 102(b) ARE OVERCOME

Claims 1-6, 9, 10, and 12-14 were rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Furuyama et al. (J Cell Sci 113: 859-868, 2000; hereinafter, "Furuyama"). According to the Office Action, Furuyama relates to a method for making a basement membrane wherein cells are cultured on a support structure. The Office Action alleges that the cells

mentioned in Furuyama are fibroblast and epithelial cells having the ability to form basement membranes, wherein the structure can be collagen. This rejection is respectfully traversed.

It is respectfully pointed out that a two-prong inquiry must be satisfied in order for a Section 102 rejection to stand. First, the prior art reference must contain all of the elements of the claimed invention. See *Lewmar Marine Inc. v. Barient Inc.*, 3 U.S.P.Q.2d 1766 (Fed. Cir. 1987). Second, the prior art must contain an enabling disclosure. See *Chester v. Miller*, 15 U.S.P.Q.2d 1333, 1336 (Fed. Cir. 1990). A reference contains an enabling disclosure if a person of ordinary skill in the art could have combined the description of the invention in the prior art reference with his own knowledge of the art to have placed himself in possession of the invention. See *In re Donohue*, 226, U.S.P.Q. 619, 621 (Fed. Cir. 1985).

Applicants note that the subject matter of original claim 7 is incorporated into amended claim 1, such that claim 1 herein recites that the sugar chain coat of the support structure has β -D-glucopyranosyl nonreducing end or 2-acetoamide-2-deoxy- β -D-glucopyranosyl non reducing end. Furuyama does not teach or suggest a support structure with these disclosed sugar chains. In fact, the Office Action admits that claim 7 is free of the prior art. Therefore, claim 1, as well as dependent claims 2-6, 9, 10, and 12-14, is also free of the prior art.

Applicants further assert that Furuyama teaches that the type II alveolar epithelial cells of the reference cannot form a basement membrane when cultured alone on a fibrillar collagen substratum (see figures 3E-3H, 6B, 6D, 6F, 7B, 7D, 7F, 8B, 8D, 8F, 9B, 9D, and 9F). This occurred because the formation of the basement membrane is not due only to the presence of cells that are capable of forming a membrane, but is also due to presence of other components at sufficient concentrations which enable molecules to collide and form complexes with basement membrane formation receptors. Without the presence of the other components, the basement membrane may not form.

However, the present invention employs a different mechanism, wherein the formation of the complex comprising the receptor and the main components of the basement membrane is promoted by repeating the binding and dissociation of a sugar-chain ligand, as a shuttle ligand, with a basement membrane formation receptor. This process is illustrated in a schematic enclosed herewith. The distinct difference between the mechanism employed in the present invention and the mechanism used in Furuyama is conveyed in the amendment of claim 1, which

clarifies that the sugar-chain coat has β -D-glucopyranosyl nonreducing end or 2-acetoamide-2-deoxy- β -D-glucopyranosyl non reducing end.

The Office Action alleges that, in Furuyama, the sugar chains are contained by the culture medium and support because the support is a polysaccharide gel. Applicants argue that the polysaccharide gel mentioned in Furuyama does not provide the same effects as the sugar-chain ligands disclosed in amended claim 1. Polysaccharides are highly hydrophilic and, even if temporarily coated on collagen fibrils, will dissolve as soon as they are immersed in medium and will no longer be solid-phased to the collagen fibrils. Sugar-chains on a support require a continuous presence with an appropriate surface density and directionality to the cells. With this in mind, it is clear that sugar chains in Furuyama were not of the appropriate quantity or type, given that the formation of a basement membrane did not occur on a collagen gel without the exogenous supply of basement membrane components.

Finally, Applicants assert that Furuyama does not anticipate claim 13, which recites cell that are "basement membrane component-hyperexpressing cells into which genes of one or more types of a basement membrane component are transfected." The cells of Furuyama are Type II alveolar epithelial cells that have been immortalized with SV40-large T antigen, but are not transfected with genes of one or more basement membrane components. Hence, claim 13 is free of the prior art.

It is clear that the invention disclosed in the instant claims is not anticipated by Furuyama. Accordingly, reconsideration and withdrawal of the Section 102 rejection are respectfully requested.

1st:

The receptor binds to sugar-chain ligand, gets frozen and anchored on the basal surface, until suffering from BM components collisions

2nd

The bound ligand is replaced by the colliding BM component molecule and this complex is restricted to move laterally on the basal surface

Receptor for
BM formation

Basal surface

3rd:

The restricted BM molecule to diffuse laterally on the basal surface collides and polymerizes

**Available
sugar-chain
ligand**

**Expelled sugar-
chain ligand**

Collagen fibrils

REQUEST FOR INTERVIEW

If any issue remains as an impediment to allowance, an interview with the Examiner and SPE are respectfully requested and the Examiner is additionally requested to contact the undersigned to arrange a mutually convenient time and manner for such an interview.

CONCLUSION

In view of the remarks and amendments herewith, the application is in condition for allowance. Favorable reconsideration of the application and prompt issuance of a Notice of Allowance are earnestly solicited. The undersigned looks forward to hearing favorably from the Examiner at an early date, and, the Examiner is invited to telephonically contact the undersigned to advance prosecution.

Respectfully submitted,
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